

Certificate of Analysis

Product name: Argininum apyrogen
Batch number / Weight: 23F15-B07-235005 / 100 G
Analysed according to: Ph.Eur.11.2
Number of analysis / Inspection Code 23F15-B07 / INS-23-5403
Reference Code / No.: V01167 / 22063661

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+25,5 - +28,5	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / <=BY6	Conform		
Specific optical rotation	+25,5 - +28,5	+27,1		
Ninhydrin-positive substances	Conform	Conform	%	
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=10	<10	ppm	
Loss on drying	<=0,5	0,26	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Arginine	98,5 - 101,0	100,08	%	
Endotoxins	<=6	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, EI Spol

Release:

Agnieszka Pszczółka

Qualified Person

28-11-2023

Expiration: 16-06-2025

Conclusion: APPROVED

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